Election #11
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PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re application of

Masaki YUI et al.

Serial No. 09/509,994 GROUP 1653

Filed May 8, 2000 Examiner H. Schnizer

METHOD FOR KEEPING THE QUALITY OF AQUEOUS PARENTERAL SOLUTION OF THROMBOMODULIN IN STORAGE AND DISTRIBUTION

RESPONSE TO LACK OF UNITY DETERMINATION

Commissioner for Patents

Washington, D.C. 20231

Sir:

Responsive to the preliminary determination of lack of unity set forth in the Official Action of March 25, 2002, applicants hereby provisionally elect Group I, claims 1-19, drawn to a method for preparing and maintaining the quality of an aqueous preparation of thrombomodulin during storage, with traverse.

The requirement is improper and should not be repeated, however, for the following reasons:

1. All of the pending claims in the present national stage application were subject to examination during the international phase of the PCT application. The International Examiner found no lack of unity, applying the same legal standard to the identical facts. Therefore, the U.S. Patent Office cannot now contend that examination of the pending claims in the present application would pose an undue burden. Indeed, the U.S.

Examiner has a considerable benefit of the search results generated by the International Examiner, on the basis of all the pending claims.

Furthermore, the Official Action does not explain why, applying the identical legal standards to the identical claims, the opposite result is now being reached in the present U.S. national phase application, relative to the international application.

2. The Official Action does not comply with the requirements of PCT Rules 13.1 and 13.2, in seeking to justify the lack of unity determination. Specifically, the definition of "special technical feature" in PCT Rule 13.2 is art based. Therefore, a proper lack of unity determination would require citation of a reference. No such citation having been made, the lack of unity determination is improper as a matter of law.

It is apparent that all of the claims share an extensive and detailed common core or special technical feature, which renders a lack of unity determination between claims 1-19 and 20-21 of the present invention entirely inappropriate. Specifically, Group I, claims 1-19 and Group II, claims 20 and 21, feature the common core of a stable, aqueous injection preparation of thrombomodulin.

In light of the above discussion, therefore, it is believed that the applicants are entitled to an action on the merits of all of the claims, and their full scope, in the present

application. Such action is accordingly respectfully requested.

Respectfully submitted,

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